

AMENDED IN ASSEMBLY APRIL 13, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 2077

Introduced by Assembly Member Solorio

February 18, 2010

~~An act to amend Section 4029 of, and to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor. An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, as amended, Solorio. ~~Centralized hospital packaging pharmacies. Pharmacy.~~

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located *and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of*

delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription. A knowing violation of the Pharmacy Law is a crime.

~~This bill would authorize a centralized hospital packaging pharmacy, as defined, to prepare medications, by performing specified functions, for administration only to patients within its own general acute care hospital and one or more general other acute care hospitals if the hospitals are under common ownership, in California, and within a 100 mile radius of the pharmacy. The bill would prohibit a person from conducting a centralized hospital packaging pharmacy without a specialty license from the board and would require applicants to apply annually to the board on forms developed by the board. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license and because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.~~

~~The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that drugs prepared in advance of receipt of a patient specific prescription shall meet specified standards, that medications be barcoded to be readable at the patient's bedside, and that medication labels contain specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located in another physical plant on the same premises or on a separate premises regulated under a hospital's license. The bill would eliminate the conditions of

licensure by the board that limit the services provided by the pharmacy in the other physical plant. The bill would also provide that a “manufacturer” does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order.

Vote: majority. Appropriation: ~~yes~~-no. Fiscal committee: yes.
State-mandated local program: ~~yes~~-no.

The people of the State of California do enact as follows:

1 *SECTION 1. The Legislature makes the following findings and*
2 *declarations:*
3 *(a) Hospitals have been encouraged to move toward the use of*
4 *automation and bedside barcode checking to improve the safety*
5 *and efficiency of drug distribution and administration to patients.*
6 *For many hospitals, the technology to enable them to achieve this*
7 *patient-safety goal is cost prohibitive.*
8 *(b) Many drugs received from manufacturers are not in the*
9 *proper unit dose for immediate administration to patients, and are*
10 *not barcoded. As a result, individual hospitals must locally prepare*
11 *and package these drugs or contract with a packager, that is not*
12 *licensed by either the California State Board of Pharmacy or*
13 *managed by a pharmacist-in-charge who is licensed by the*
14 *California State Board of Pharmacy, to do so.*
15 *(c) The Business and Professions Code definition of drug*
16 *“manufacturer” allows one hospital pharmacy to compound and*
17 *package medications for another hospital only for specific patients,*
18 *without being licensed as a manufacturer. This restriction does*
19 *not support the most current hospital drug distribution processes,*
20 *nor does it accommodate innovations that will improve patient*
21 *safety.*
22 *(d) The federal Food and Drug Administration (FDA) has*
23 *amended its position to allow hospitals under common control*
24 *and operating within a state to consolidate resources at a single*
25 *location for timely, economic repackaging and distribution with*
26 *greater, more dedicated expertise, without becoming federally*
27 *registered manufacturers for those products. This FDA action is*

1 *in recognition that the compounding and repackaging activity is*
2 *not truly drug manufacturing.*

3 *(e) A centralized pharmacy compounding and packaging*
4 *operations approach allows hospitals to take advantage of*
5 *high-speed automated equipment, economies of scale, space*
6 *efficiencies, and more consistent standardized quality control*
7 *systems. Likewise, a centralized licensed pharmacy approach*
8 *allows for greater regulatory control via the pharmacist-in-charge*
9 *and greater assurance of safety by concentrating the professional*
10 *expertise among a centralized management, staff, and quality*
11 *assurance program.*

12 *(f) Centralization of the packaging operations as a licensed*
13 *pharmacy under the license of a hospital, rather than as a*
14 *“manufacturer,” assures the patient-safety oversight of the*
15 *California State Board of Pharmacy and other hospital regulatory*
16 *and accreditation bodies, and adherence to the new stronger*
17 *pharmacy compounding regulations.*

18 *SEC. 2. Section 4029 of the Business and Professions Code is*
19 *amended to read:*

20 4029. (a) “Hospital pharmacy” means and includes a pharmacy,
21 licensed by the board, located within any licensed hospital,
22 institution, or establishment that maintains and operates organized
23 facilities for the diagnosis, care, and treatment of human illnesses
24 to which persons may be admitted for overnight stay and that meets
25 all of the requirements of this chapter and the rules and regulations
26 of the board.

27 (b) A hospital pharmacy also includes a pharmacy, *licensed by*
28 *the board*, that may be located outside of the hospital, in another
29 physical plant *on the same premises or on a separate premises*
30 that is regulated under a hospital’s ~~consolidated license issued~~
31 ~~pursuant to Section 1250.8 of the Health and Safety Code. As a~~
32 ~~condition of licensure by the board, the pharmacy in another~~
33 ~~physical plant shall provide pharmaceutical services only to~~
34 ~~registered hospital patients who are on the premises of the same~~
35 ~~physical plant in which the pharmacy is located. The pharmacy~~
36 ~~services provided shall be directly related to the services or~~
37 ~~treatment plan administered in the physical plant. Nothing in this~~
38 ~~paragraph subdivision shall be construed to restrict or expand the~~
39 services that a hospital pharmacy may provide.

1 SEC. 3. *Section 4033 of the Business and Professions Code is*
2 *amended to read:*

3 4033. (a) (1) “Manufacturer” means and includes every person
4 who prepares, derives, produces, compounds, or repackages any
5 drug or device except a pharmacy that manufactures on the
6 immediate premises where the drug or device is sold to the ultimate
7 consumer.

8 (2) Notwithstanding paragraph (1), “manufacturer” shall not
9 mean a pharmacy compounding *and repackaging* a drug for
10 parenteral therapy, ~~pursuant to a prescription, or oral therapy in~~
11 ~~a hospital~~ for delivery to another pharmacy *or hospital* for the
12 purpose of ~~delivering~~ *dispensing* or administering the drug,
13 ~~pursuant to a prescription or order,~~ to the patient or patients named
14 in the prescription, ~~provided that neither the components for the~~
15 ~~drug nor the drug are compounded, fabricated, packaged, or~~
16 ~~otherwise prepared prior to receipt of the prescription or order.~~

17 (3) Notwithstanding paragraph (1), “manufacturer” shall not
18 mean a pharmacy that, at a patient’s request, repackages a drug
19 previously dispensed to the patient, or to the patient’s agent,
20 pursuant to a prescription.

21 (b) Notwithstanding subdivision (a), as used in Sections 4034,
22 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer”
23 means a person who prepares, derives, manufactures, produces,
24 or repackages a dangerous drug, as defined in Section 4022, device,
25 or cosmetic. Manufacturer also means the holder or holders of a
26 New Drug Application (NDA), an Abbreviated New Drug
27 Application (ANDA), or a Biologics License Application (BLA),
28 provided that such application has been approved; a manufacturer’s
29 third party logistics provider; a private label distributor (including
30 colicensed partners) for whom the private label distributor’s
31 prescription drugs are originally manufactured and labeled for the
32 distributor and have not been repackaged; or the distributor agent
33 for the manufacturer, contract manufacturer, or private label
34 distributor, whether the establishment is a member of the
35 manufacturer’s affiliated group (regardless of whether the member
36 takes title to the drug) or is a contract distributor site.

37 ~~SECTION 1. Section 4029 of the Business and Professions~~
38 ~~Code is amended to read:~~

39 ~~4029. (a) “Hospital pharmacy” means and includes a pharmacy;~~
40 ~~licensed by the board, located within any licensed hospital,~~

1 institution, or establishment that maintains and operates organized
2 facilities for the diagnosis, care, and treatment of human illnesses
3 to which persons may be admitted for overnight stay and that meets
4 all of the requirements of this chapter and the rules and regulations
5 of the board.

6 (b) ~~A hospital pharmacy also includes a pharmacy that may be
7 located outside of the hospital, in another physical plant that is
8 regulated under a hospital's consolidated license issued pursuant
9 to Section 1250.8 of the Health and Safety Code. As a condition
10 of licensure by the board, the pharmacy in another physical plant
11 shall provide pharmaceutical services only to registered hospital
12 patients who are on the premises of the same physical plant in
13 which the pharmacy is located, except as provided in Article 7.6
14 (commencing with Section 4128). The pharmacy services provided
15 shall be directly related to the services or treatment plan
16 administered in the physical plant. Nothing in this subdivision
17 shall be construed to restrict or expand the services that a hospital
18 pharmacy may provide.~~

19 SEC. 2. ~~Article 7.6 (commencing with Section 4128) is added
20 to Chapter 9 of Division 2 of the Business and Professions Code,
21 to read:~~

22
23 Article 7.6. Centralized Hospital Packaging Pharmacies
24

25 4128. (a) ~~Notwithstanding Section 4029, a centralized hospital
26 packaging pharmacy may prepare medications, by performing the
27 following specialized functions, for administration only to patients
28 within its own general acute care hospital and one or more other
29 general acute care hospitals if the hospitals are (1) under common
30 ownership, (2) in California, and (3) located within a 100-mile
31 radius of the centralized hospital packaging pharmacy.~~

32 (1) ~~Preparing unit dose packages for single administration to
33 patients from bulk containers, if each unit dose package is barecoded
34 to contain at least the information required by Section 4128.4.~~

35 (2) ~~Preparing compounded unit dose drugs for parenteral therapy
36 for administration to patients, if each compounded unit dose drug
37 is barecoded to contain at least the information required by Section
38 4128.4.~~

1 ~~(3) Preparing compounded unit dose drugs for administration~~
2 ~~to patients, if each unit dose package is barecoded to contain at least~~
3 ~~the information required by Section 4128.4.~~

4 ~~(b) For the purposes of this article, a “centralized hospital~~
5 ~~packaging pharmacy” means a licensed hospital pharmacy located~~
6 ~~within a general acute care hospital, as defined in subdivision (a)~~
7 ~~of Section 1250 of the Health and Safety Code.~~

8 ~~4128.1. (a) No person shall conduct a centralized hospital~~
9 ~~packaging pharmacy unless it has obtained a specialty license from~~
10 ~~the board.~~

11 ~~(b) A licensed hospital pharmacy serving only its own patients~~
12 ~~shall not be required to obtain a specialty license as described in~~
13 ~~subdivision (a).~~

14 ~~4128.2. (a) In addition to the pharmacy license requirement~~
15 ~~described in Section 4110, a centralized hospital packaging~~
16 ~~pharmacy shall obtain a specialty license from the board prior to~~
17 ~~engaging in the functions described in Section 4128.~~

18 ~~(b) An applicant seeking a specialty license pursuant to this~~
19 ~~article shall apply to the board on forms established by the board.~~

20 ~~(c) Before issuing the specialty license, the board shall inspect~~
21 ~~the pharmacy and ensure that the pharmacy is in compliance with~~
22 ~~this article and regulations established by the board.~~

23 ~~(d) A license to perform the functions described in Section 4128~~
24 ~~may only be issued to a pharmacy that is licensed by the board as~~
25 ~~a hospital pharmacy.~~

26 ~~(e) A license issued pursuant to this article shall be renewed~~
27 ~~annually and is not transferrable.~~

28 ~~(f) An applicant seeking renewal of a specialty license shall~~
29 ~~apply to the board on forms established by the board.~~

30 ~~(g) A license to perform the functions described in Section 4128~~
31 ~~shall not be renewed until the pharmacy has been inspected by the~~
32 ~~board and found to be in compliance with this article and~~
33 ~~regulations established by the board.~~

34 ~~(h) The fee for issuance or annual renewal of a centralized~~
35 ~~hospital packaging pharmacy license shall be six hundred dollars~~
36 ~~(\$600) and may be increased by the board to eight hundred dollars~~
37 ~~(\$800).~~

38 ~~4128.3. A centralized hospital packaging pharmacy may prepare~~
39 ~~and store a limited quantity of the unit dose drugs authorized by~~
40 ~~Section 4128 in advance of receipt of a patient specific prescription~~

1 in a quantity as is necessary to ensure continuity of care for an
2 identified population of patients of the general acute care hospital
3 based on a documented history of prescriptions for that patient
4 population. The expiration date for these drugs shall meet
5 established compendium standards as stated in the United States
6 Pharmacopoeia and other widely accepted references.

7 4128.4. Any unit dose medication produced by a centralized
8 hospital packaging pharmacy shall be barcoded to be readable at
9 the patient's bedside. The bar code shall contain at least the
10 following information:

11 (a) Expiration date.

12 (b) Lot number or control number.

13 (c) National Drug Code Directory number.

14 4128.5. The label for each unit dose medication produced by
15 a centralized hospital packaging pharmacy shall contain all of the
16 following information:

17 (a) Expiration date.

18 (b) Established name of the drug.

19 (c) Quantity of the active ingredient.

20 (d) Special storage or handling requirements.

21 (e) Name of the packaging pharmacy.

22 4128.6. All compounding and packaging functions specified
23 in Section 4128 shall be performed only in the licensed centralized
24 hospital packaging pharmacy and that pharmacy shall comply with
25 all applicable regulations, including, but not limited to, regulations
26 regarding compounding and when appropriate, sterile injectable
27 compounding.

28 4128.7. A centralized hospital packaging pharmacy and the
29 pharmacists working in the pharmacy shall be responsible for the
30 integrity, potency, quality, and labeled strength of any unit dose
31 drug product prepared by the centralized hospital packaging
32 pharmacy.

33 SEC. 3. No reimbursement is required by this act pursuant to
34 Section 6 of Article XIII B of the California Constitution because
35 the only costs that may be incurred by a local agency or school
36 district will be incurred because this act creates a new crime or
37 infraction, eliminates a crime or infraction, or changes the penalty
38 for a crime or infraction, within the meaning of Section 17556 of
39 the Government Code, or changes the definition of a crime within

1 ~~the meaning of Section 6 of Article XIII B of the California~~
2 ~~Constitution.~~

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